

REMARKS

Claims 1-38 are pending in this application and remain for consideration.

Claims 20-38 were allowed.

Claims 1-19 were rejected under the first paragraph of 35 U.S.C. § 112 for lack of enablement.

Claims 1-19 were rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness.

Reexamination of the application as amended, reconsideration of the rejections, and allowance of the claims not already allowed are respectfully requested.

The three-month shortened statutory period for response expires on July 24, 2006. Accordingly, this response is being filed in a timely manner.

This response is being filed in accordance with recently revised 37 C.F.R. § 1.121, as set forth in 68 F.R. 38611 (June 30, 2003). If the amendment is considered to be not in compliance with recently revised 37 C.F.R. § 1.121, the Examiner is respectfully requested to contact the undersigned at his earliest possible convenience.

I. AMENDMENTS TO THE APPLICATION

Entry of the amendments to the claims is respectfully requested. As detailed below, the amendments introduce no new matter.

Claim 1 is amended to clarify the definition of Soma as recited in the specification at paragraph [0018] as well as the preparation of the extract of Soma as recited in the specification at paragraph [0019].

A similar amendment is made to claim 7.

These amendments are made solely to address the issues remaining with respect to the first and second paragraphs of 35 U.S.C. § 112 and for no other reason. Although Applicants assert that the claims as originally filed are both enabled and definite, these amendments are made to advance prosecution.

Other minor amendments are made for grammatical consistency. These amendments do not affect the substance or scope of the claims.

Accordingly, entry of these amendments to the claims is respectfully requested.

II. THE REJECTIONS UNDER THE FIRST PARAGRAPH OF 35 U.S.C. § 112 FOR LACK OF ENABLEMENT

Claims 1-19 were rejected under the first paragraph of 35 U.S.C. § 112 for lack of enablement.

As applied to the amended claims after amendments were made to the independent claims, claims 1 and 7, this rejection is respectfully traversed.

Specifically, the rejection was made because the specification failed to teach what the term “the plant Soma” actually defined, so that one of ordinary skill in the art could not make and use the invention. More specifically, the application failed to teach one of ordinary skill in the art to prepare “an aqueous extract” of Soma.

This rejection is respectfully traversed. Regardless of what certain authorities may have considered “the plant Soma,” the present application presents a source for a specific plant preparation and a method of making aqueous extracts of that plant. The resulting compositions have been shown to have therapeutic efficacy. Moreover, the claims as amended recite characteristics of the plant Soma recited in the specification. These characteristics are accepted by those of ordinary skill in the art as identifying characteristics. There is no evidence that has been provided in the Office Action or otherwise that suggests that these identifying characteristics are inaccurate or that the use of these identifying characteristics leads to an incorrect identification of the plant or to an identification of a plant that does not have the required characteristics or is inactive in compositions according to the present invention.

The burden of the Patent and Trademark Office to show non-enablement has not been met for this rejection, because the statements cited in the Office Action expressing doubt about the identity of Soma do not counter the actual examples and results cited in the specification. This is particularly true in view of the identification of the plant provided in the specification, the recitation of the method of preparation of the extract also provided in the specification, and the results.

It is established law with respect to enablement that the specification must be taken as being in compliance with the first paragraph of 35 U.S.C. § 112 unless there is reason to doubt the objective role of the statements contained in the specification which must be relied upon for enabling support. In re Marzocchi, 169 U.S.P.Q. 367 (C.C.P.A. 1971). Here, any uncertainty as to the identity of the plant involved is overcome by the actual teachings of the specification, which recite the preparation of an extract of the plant in question and its administration to a cancer patient. The identity of the plant actually used is not in doubt in view of the teachings of the specification.

The fact that there may have been some uncertainty over the identity of “the plant Soma” created by the commentary of others does not change the facts recited in the

specification. It is well established that the patentee can be his own lexicographer. Hormone Research Foundation, Inc. v. Genentech, Inc. 15 U.S.P.Q. 2d 1039, 1043 (Fed. Cir. 1990), cert. dismissed, 499 U.S. 955 (1991). All that is required for the patentee to be his own lexicographer is “reasonable clarity, definiteness and precision” in the definition of specific terms used in the specification. In re Paulsen, 31 U.S.P.Q. 2d 1671, 1674 (Fed. Cir. 1994). The specification is internally consistent and the use of the term “the plant Soma” does not create an inconsistency between what would be understood by one of ordinary skill in the art and the teachings of the specification. This is particularly true in light of the identification of the characteristics of the plant referred to in the specification as “the plant Soma.” The specification, including the examples, considered as a whole, clearly meet the standard required by the first paragraph of 35 U.S.C. § 112.

Moreover, properly reasoned and supported statements explaining any failure to comply with the enablement requirements of 35 U.S.C. § 112 are a requirement to properly support such a rejection. In re Wright, 27 U.S.P.Q. 2d 1510 (Fed. Cir. 1993). The question is not whether there existed, in the past, some doubt about the identity of Soma. The question, from the standpoint of compliance with the enablement requirement of the first paragraph of 35 U.S.C. § 112, is whether the specification, including the examples, enables one of ordinary skill in the art to prepare a particular plant extract and use it to treat cancer or other conditions set forth in the specification. The answer, in view of the specification and examples, to this question is undoubtedly affirmative. The statements in the Office action expressing possible doubt as to the identity of Soma do not rise to the level of statements that create a sufficient level of doubt that one of ordinary skill in the art could practice the claimed invention without undue experimentation. This is particularly true in light of the detail provided in the specification, including identifying characteristics of the plant.

The specification need not recite details of the claimed invention where one of ordinary skill in the art would consider these details obvious or well known in the art. In re Skirvan, 166 U.S.P.Q. 85 (C.C.P.A. 1970). The quantity of detail that is permitted to be omitted can be substantial when the state of the art is such that the detail could be readily

supplied by one of ordinary skill in the art. This is true even if no working examples are furnished. In re Strahilevitz, 212 U.S.P.Q. 561 (C.C.P.A. 1982) (immunochemistry). It then follows that the presence of working examples strengthens the case for enablement, particularly where, as here, there has been no challenge to the results presented in the working examples.

Even should considerable experimentation be required, this does not constitute “undue experimentation” if the experimentation required is routine and the worker is given sufficient guidance. “[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.” In re Colianni, 195 U.S.P.Q. 150, 153 (C.C.P.A. 1977). Moreover, complete reproducibility is not required to find enablement. Johns Hopkins University v. CellPro, Inc., 47 U.S.P.Q. 2d 1705 (Fed. Cir. 1998). There has been absolutely no suggestion that the results provided in the specification, including the examples, lack reproducibility.

The degree of unpredictability must be considered within the context of the invention and the knowledge of those skilled in the art. Even broad claims can be enabled if the subject matter of the claims is such that the unpredictability of what is actually claimed is minimized. See In re Vaeck, 20 U.S.P.Q. 2d 1438, 1444-45 (Fed. Cir. 1991) (claims directed to expression of chimeric genes in specific genera of cyanobacteria allowable even though claims were not limited to expression of genes encoding particular *Bacillus* proteins in view of extensive understanding in the prior art of toxicity of *Bacillus* proteins). The skill of those of ordinary skill in the art clearly encompasses the preparation and use of herbal compositions such as those recited in the claims at issue. Again, there has been no suggestion in the Office Action that those of ordinary skill in the art would be unable to prepare or use the compositions that are recited in claims 1-19.

All that is required to provide enable is that any mode of making and using the invention be recited in the specification. Engel Industries, Inc. v. Lockformer Corp., 20 U.S.P.Q. 2d 1300 (Fed. Cir. 1991). This standard is clearly met here by the examples of particular herbal compositions described in the specification and examples of their use.

Specific directions for the preparation and use of these compositions are given. No more is required to establish enablement under the first paragraph of 35 U.S.C. § 112. One of ordinary skill in the art can readily obtain the plant Soma as described in the specification of the patent application and can prepare and use the compositions specified by the claims.

Moreover, there is no requirement that all compositions within the scope of the claimed methods provide the same degree of efficacy for cancer treatment. In re Gardner, 177 U.S.P.Q. 396 (C.C.P.A. 1973); In re Fouche, 169 U.S.P.Q. 429 (C.C.P.A. 1971).

As is frequently the case in enablement questions, a review of the factors set forth by the Federal Circuit in In re Wands, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988), is useful. The Wands factors are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. Id.

A review of these factors indicates that enablement is present and that there is no basis for a rejection of claims 1-19 on the grounds of lack of enablement under the first paragraph of 35 U.S.C. § 112. Any possible speculation about the accuracy or inaccuracy of previous identifications of “the plant Soma” does not change this conclusion. All that matters is that one of ordinary skill in the art could identify and obtain the plant identified as “the plant Soma” in the specification, prepare an extract as specified in the specification, and use the extract as specified in the specification. Nothing else is required for enablement under the first paragraph of 35 U.S.C. § 112.

The quantity of experimentation required is not excessive in view of the subject matter. The compositions to be used, and their preparation, are described in detail. A source for the plant is described. These teachings require little experimentation to be carried out by one of ordinary skill in the art.

The amount of direction or guidance presented in the specification is substantial. This direction or guidance includes the information, as described above, with respect to the methods for the preparation of compositions including extracts of Soma and methods for treatment. The plant to be used is described by its botanical characteristics.

The nature of the invention is such that undue experimentation is not present, when the scope of the claimed invention is taken into account. The claimed invention, from the standpoint of enablement, is of a relatively restricted scope. Moreover, the functional language recited in claims 1 and 7, and applying to well to the dependent claims, must be taken into account in evaluating the existence of enablement. In re Halleck, 164 U.S.P.Q. at 647. These are not claims for which a degree of extrapolation is required such that the extrapolation would lead to a conclusion of undue experimentation based on the burden placed on one of ordinary skill in the art to achieve enablement within the scope of the claimed invention. Compare In re Strahilevitz, 212 U.S.P.Q. 561 (C.C.P.A. 1982) (enablement found even though no working examples present) with In re Fisher, 166 U.S.P.Q. 18 (C.C.P.A. 1970) (no enablement for claims to an ACTH preparation having a potency of at least 1 international unit/mg, with no upper limit, when specification disclosed preparation of ACTH of potency between 1.11 and 2.30 international units/mg). Here, the scope of the protection sought is relatively circumscribed and the degree of experimentation required is minimal.

In fact, the Federal Circuit itself, in Wands, found that enablement existed and that undue experimentation was not present. It held that "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 8 U.S.P.Q. 2d at 1404. The evidence referred to strongly indicates that the amount of experimentation required to reproduce the claimed subject matter would be routine. The speculation cited by the Examiner with regard to any possible uncertainty as to the identification of "the plant Soma" does not change this conclusion. Moreover, the specification provides a great deal of detailed

guidance with respect to whatever experimentation might actually be required, including a source for Soma and botanical descriptions of the plant.

As long as the specification discloses at least one method for making and using the claimed invention that bears a "reasonable correlation" to the entire scope of the claimed invention, the enablement requirement of the first paragraph of 35 U.S.C. § 112 is satisfied. In re Fisher, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970). That test is met here in view of the teachings of the Examples, including the teaching of a specific source for Soma.

The situation here is analogous to that in Wands. The claims are of such a scope that one of ordinary skill in the art could use the claimed invention with a high probability of success, notwithstanding any uncertainty in the identification of Soma. That uncertainty does not create additional experimentation for the practitioner; it is of no practical effect. In any event, it is mitigated by the specific disclosure of a commercial source of Soma in the specification as well as by the botanical descriptions of the plant Soma, usable to identify the plant.

Again, it is highly unlikely that one of ordinary skill in the art would be guided by the articles referred to by the Examiner. Such a person of ordinary skill in the art would be guided by the specification, including the examples. Again, it must be emphasized that a source for Soma is identified in the specification, and there has been no evidence presented that that Soma is not available from that source. There is also no evidence that the characteristics of Soma presented in the specification would lead one of ordinary skill in the art to a plant that lacked the activity required. When the specification is taken into account, the claims are enabled throughout their entire scope.

The comments made in the Office Action at page 3 regarding the "great confusion and controversy" as to what constitutes the plant Soma do not give rise to a lack of enablement under the first paragraph of 35 U.S.C. § 112. There is no basis for the suggestion that the plant Soma is *Amanita muscaria* or any other type of mushroom. This does not create undue experimentation, and one of ordinary skill in the art could readily

Accordingly, the Examiner is respectfully requested to withdraw this rejection as applied to the amended claims.

III. THE REJECTIONS UNDER THE SECOND PARAGRAPH OF 35 U.S.C. § 112 FOR INDEFINITENESS

Claims 1-19 were rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness.

As applied to the amended claims after amendments were made to the independent claims, claims 1 and 7, this rejection is respectfully traversed.

With respect to the rejection under the second paragraph of 35 U.S.C. § 112, the recitation of "the plant Soma" in claims 1-16 does not make these claims vague or indefinite.

These claims particularly point out and distinctly claim what the inventor regards as his invention. The foregoing argument establishes that the identification of "the plant Soma" in the specification, including the examples, is sufficient to enable one of ordinary skill in the art to identify the plant, prepare the composition including the herbal preparation for administration, and administer the composition. This means that claims reciting this element are not indefinite when considered from the standpoint of one of ordinary skill in the art. That is all that is required. There is no arbitrary standard of "precision and definiteness," defined in a vacuum, that claim language is required to meet. The claim language, including any recitation of "the plant Soma," cannot be read in a vacuum or by itself, but must be considered in light of the specification and of the teachings of the art. "[T]he definiteness of the language must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art."

In re Moore, 169 U.S.P.Q. 236, 238 (C.C.P.A. 1971). In view of the detailed teaching of the specification, including the recitation of a readily available source for Soma and botanical information about the plant and its characteristics, there is no basis for a rejection of any of these claims on the grounds of indefiniteness. The articles cited by the Examiner do not provide the basis for a rejection on the grounds of indefiniteness.

When language serves reasonably to describe the claimed subject matter to those of skill in the field of the invention and to distinguish the claimed subject matter from the prior art, it should not be subject to rejection under the second paragraph of 35 U.S.C. § 112 on the grounds of indefiniteness. Andrew Corp. v. Gabriel Electronics, Inc., 6 U.S.P.Q. 2d 2010, 2012 (Fed. Cir. 1988). Such claim language must always be interpreted in light of the state of the art and the understanding of those skilled in the art. Hybritech, Inc. v. Abbott Laboratories, 4 U.S.P.Q. 2d 1001, 1011 (C.D. Calif. 1987), *affd*, 7 U.S.P.Q. 2d 1191 (Fed. Cir. 1988) (claim referred to minimum "affinity" of monoclonal antibodies; even though claim did not specify whether "functional affinity" or "intrinsic affinity" was intended, the evidence indicated that the patentee would likely be able to prove that "someone tutored in the art would understand it to mean functional affinity").

The same argument holds sway here. One of ordinary skill in the art would understand that "the plant Soma" is the plant that is used in the herbal preparations of the examples and that preparation is the one that exerts the beneficial effects recited in the claims. This is the same plant for which a commercial source is recited in the specification and for which a description is also recited in the specification. Accordingly, one of ordinary skill in the art would understand that this is what is meant by "the plant Soma" in these claims and would use that plant, as described in the specification, to prepare the compositions recited in these claims. Any commentary to the contrary, including the articles cited by the Examiner, can safely be disregarded.

Moreover, as long as the meaning of the claim language is clear, the patentee is entitled to be his own lexicographer. Lear Siegler, Inc. v. Aeroquip Corp., 221 U.S.P.Q. 1025 (Fed. Cir. 1984); Fromson v. Advance Offset Plate, Inc., 219 U.S.P.Q. 1137 (Fed. Cir.

1983). Thus, the recitation of “the plant Soma” in the claims does not offend the generally accepted meaning of the phrase and is sufficiently clear and definite.

Therefore, if the claims, read in light of the specification, reasonably apprise those skilled in the art of the use and scope of the invention, and if the language is as precise as the subject matter permits, the second paragraph of 35 U.S.C. § 112 demands no more. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986) (interpretation of a limitation specifying a numerical value for antibody affinity where the method of calculation was known in the art at the time of filing to be imprecise did not result in indefiniteness), cert. denied, 489 U.S. 947 (1987).

Thus, the articles and other references cited by the Examiner do not make the term “the plant Soma” uncertain within the context of the claims as interpreted in light of the specification. That is all that is required by the second paragraph of 35 U.S.C. § 112. Nothing more is required by that section of the statute, and Applicant should not be penalized because of a controversy about the use of the term “the plant Soma” when the specification makes it clear what plant is intended.

Applicants are not making a circular argument. The plant is commercially available, and what is commercially available and is recited as such is what is used in the claimed methods. Moreover, the characteristics of the plant are defined in the specification, and the plant that conforms to those characteristics is the plant that is used in compositions and methods of the present invention. The use of the term “the plant Soma” does not contravene the basic rule that a patentee can be his own lexicographer as long as the terminology used makes clear the boundaries of the subject matter for which protection is sought. M.P.E.P. § 2173.01. A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is being sought. In re Swinehart, 439 F.2d 210, 160 U.S.P.Q. 226 (C.C.P.A. 1971). The fact that some uncertainty has existed in the past about the meaning of the term “the plant Soma” should not preclude Applicants from using this term in the patent application.

The comments made in the Office Action at page 5-8, as with the rejection under the first paragraph of 35 U.S.C. § 112, do not lead to the conclusion that the claims are indefinite. As emphasized above, sufficient information is provided in the specification to identify the plant, and a commercial source is recited. That is all that is required by the second paragraph of 35 U.S.C. § 112.

Therefore, there is no basis for a rejection of these claims under the second paragraph of 35 U.S.C. § 112. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. CONCLUSION

In conclusion, claims 20-38 are already allowed. Claims 1-19 are enabled by the specification and particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Accordingly, prompt allowance of claims 1-19 is respectfully requested.

Respectfully submitted,

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